UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL NO. 1456
	CIVIL ACTION NO. 01-CV-12257-PBS
THIS DOCUMENT RELATES TO	Judge Patti B. Saris
State of Montana v. Abbott Labs. Inc., et al., No. 02-CV-12084-PBS D. Mont. Cause No. CV-02-09-H-DWM	
State of Nevada v. American Home Products, et al., CA No. CV-12086-PBS D. Nev. Cause No. CV-N-02-0202-ECR	

AFFIDAVIT OF STEPHEN KNOWLES

I, Stephen Knowles, being over eighteen years of age and competent to testify herein, state and attest as follows:

1. My name is Stephen S. Knowles. I am currently employed by Astellas US LLC ("Astellas") as Senior Director, Accounting and Taxation.

2. Prior to my employment with Astellas, I was employed by Fujisawa Healthcare, Inc. ("FHI") from April 1, 1998 to March 31, 2005 as Senior Director, Accounting and Taxation. Prior to that, I was employed by Fujisawa USA, Inc. ("FUSA") from April 1, 1990 to March 31, 1998 as Director, Accounting.

3. FUSA was a Delaware corporation headquartered in Deerfield, Illinois. It was dissolved in December, 1998. Prior to its dissolution, it manufactured and sold branded and generic drugs.

4. FHI was a Delaware corporation headquartered in Deerfield, Illinois. It was dissolved in March, 2005. It manufactured and sold only branded drugs. Both FUSA and FHI

were formerly wholly owned subsidiaries of Fujisawa Pharmaceutical Co., Ltd., a company organized under the laws of Japan and publicly traded in Japan.

5. On April 1, 2005, FHI was merged into a Delaware corporation now known as Astellas U.S. Holding, Inc. Its parent is a Japanese corporation, Astellas Pharma Inc. Astellas is the successor company to FUSA and FHI, the entities named in the litigation for which I have provided this Affidavit.

6. On May 31, 1998, FUSA sold its generic drug business to American Pharmaceutical Partners ("APP"). APP is a company incorporated in the state of Delaware, and is completely separate and distinct from FUSA, FHI and Astellas. APP has not been named as a defendant in this litigation.

7. The sale of FUSA's generic business to APP was an "arms length" transaction. It included the transfer of all equipment, personnel and records involved in manufacture and sale of every generic drug manufactured by FUSA. These drugs included the following drugs named in this litigation: acyclovir sodium; dexamethasone sodium phosphate; doxorubicin hydrochloride; fluorouracil; gentamicin sulfate; vinblastine sulfate; and lyphocin/vancomycin hydrocholoride.

8. None of the drugs listed in the previous paragraph have been manufactured or sold by FUSA, FHI or Astellas since May 31, 1998. After May 31, 1998, Fujisawa did not retain any authority or legal responsibility for transactions involving the drugs listed above. To my knowledge, no representation as to the price of the drugs listed in the previous paragraph were made by FUSA, FHI or Astellas since May 31, 1998, except to the extent such representations were necessary in connection with sales made prior to May 31, 1998.

9. Among the drugs that Fujisawa has manufactured, many are "multi-source" drugs. This means that Fujisawa is not the only manufacturer and/or distributor of the drugs. The drugs have multiple manufacturers or packagers, and no longer have trademark or patent protection by

Fujisawa. Among the drugs identified in the Complaint in this litigation, the following are multi-source drugs: acyclovir sodium; Aristocort® (triamcinilone, triamcinilone diacetate or triamcinilone acetonide); Aristospan® (triamcinilone hexacetonide); Cefizox ® (ceftizomine sodium or ceftizoxime in d5w), Cyclocort® (amcinonide); dexameth-asone sodium phosphate; doxorubicin hydrochloride; flourouracil; gentamicin sulfate; Lyphocin® (vancomycin hydrochloride); NebuPent® (pentamidine isethionate); Pentam 300 ® (pentamidine isethionate); and vinblastine sulfate.

10. Another category of Fujisawa drugs identified in the Complaint is physician-administered drugs. These drugs must be administered by a physician or another certified care-giver (*e.g.,* by injection). The physician-administered drugs include acyclovir sodium; Aristospan® (triamcinilone hexacetonide); Cefizox® (ceftizomine sodium or ceftizoxime in d5w); dexamethasone sodium phosphate; doxorubicin hydrochloride; flourouracil; gentamicin sulfate; Lyphocin® (vancomycin hydrochloride); NebuPent® (pentamidine isethionate); Pentam 300® (pentamidine isethionate); and vinblastine sulfate.

11. The Complaint also identifies three self-administered drugs for Fujisawa. These drugs come in a form that does not have to be administered by a physician, but can be self-administered by patients (*e.g.,* by taking a pill or applying a cream). The self-administered drugs include Aristocort® (triamcinilone, triamcinilone diacetate or triamcinilone acetonide); Cyclocort® (amcinonide); and Prograf® (tacrolimus).

12. Another small class of drugs is those that only Fujisawa manufactures, and that do not have a therapeutic equivalent. These drugs include Prograf® (tacrolimus). Prograf® is an immunosuppressant used to treat transplant patients. It has fewer side effects and is not as

nephrotoxic as any drug alternative. Fujisawa is the only manufacturer or distributor of Prograf®.

13. As a pharmaceutical manufacturer, Fujisawa has no role in deciding which drugs should be prescribed to particular patients. Nor does Fujisawa provide or dispense drugs directly to patients. Therefore, Fujisawa does not receive any reimbursement on the cost of drugs from States, the federal government, government programs or any other third-party payor.

Further Affiant Sayeth Naught.

Stephen S. Knowles
Astellas US LLC

SUBSCRIBED and sworn before me this 6 day of February, 2007

Constance Edwards
NOTARY

My commission expires 3/6/09

OFFICIAL SEAL
CONSTANCE EDWARDS
NOTARY PUBLIC - STATE OF ILLINOIS
MY COMMISSION EXPIRES:03/06/09